ΑD	1

MIPR NUMBER: 92MM2549

TITLE: Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents

PRINCIPAL INVESTIGATOR: LTC Donald R. Skillman

CONTRACTING ORGANIZATION: Fitzsimons Army Medical Center Aurora, Colorado 80045-5001

REPORT DATE: April 1996

TYPE OF REPORT: Final

PREPARED FOR: Commander

U.S. Army Medical Research and Materiel Command Fort Detrick, Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;

distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

## REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

Publis-reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

Davis riighway, Suite 1204, Annigton, VA 22202-4	502, and to the office of Management un	o baagat, rapativatik tiaasatat	
1. AGENCY USE ONLY (Leave blank)			
***	April 1996		92 - 30 Apr 96)
4. TITLE AND SUBTITLE Prospec			5. FUNDING NUMBERS
Lymphocytes and Clinical	Data on HIV Infected	d	
Individuals Taking Antire	92MM2549		
	•		
6. AUTHOR(S)			
LTC Donald R. Skillman			
He bonard R. barraman			
7. PERFORMING ORGANIZATION NAME	(C) AND ADDDESS(ES)		8. PERFORMING ORGANIZATION
Fitzsimons Army Medical			REPORT NUMBER
Aurora, Colorado 80045-			
Adiola, Cololado 80045	7001		
	ALANGIO AND ADDDECCIEC		
<ol> <li>SPONSORING/MONITORING AGENCY Commander</li> </ol>	NAME(S) AND ADDRESS(ES)		10. SPONSORING/MONITORING AGENCY REPORT NUMBER
U.S. Army Medical Research	rh and Materiel Comm	and	AGENOT HELONT NOMBER
Fort Detrick, Frederick,			
FOIC Declick, Flederick,	Haryrana 21702 301	<b>-</b>	
11. SUPPLEMENTARY NOTES		- 4000	$50705~054~^{}$
11. SUPPLEMENTANT NOTES		INNE	NU/UN UN4
			101 00 00 1
40 DIOTRIPLITION / AVAILABILITY OF	ATERIT		12b. DISTRIBUTION CODE
12a. DISTRIBUTION / AVAILABILITY ST	ATEMENT		12B. DISTRIBUTION CODE
Approved for public relea			
Approved for public feres	·		
13. ABSTRACT (Maximum 200 F	AMO Infantions Discour	Camina in alanimu	2.6 June 1006 The elicial I
			3Ø June 1996. The clinical drug atients have been referred either
· · · · · · · · · · · · · · · · · · ·	•	•	atients have been referred either

funds were expended in any of these trials.

FAMC enrolled approximately 700 patients in the natural history study since its beginning. FAMC has stored, on site, almost 56,000 frozen plasma/serum/cell samples of HIV from 1986 to the present. These frozen specimens will be sent to CPT Douglas Mayer at WRAIR, to be stored at a facility designated by him for future scientific purposes. The data base, has been previously integrated into the central MMCAR data base, updated information will be sent with the frozen specimens and patient records. Patient histories had been routinely sent to Sociometrics, who we understand had been collecting this data for the U.S. Armed Forces. Copies of patient records will be sent to CPT Mayer (or his designee) for ready access to clinical information, should it be needed.

Some statistical information is being evaluated by Susan Y. J. Zhou at the Henry M. Jackson Foundation.

Results and significance of this MIPR will be decided at some time in the future. The purpose of the MIPR was to collect and save specimens of HIV from Military beneficiaries, and others included in the protocol, so that material would be available for future research.

14. SUBJECT TERMS	15. NUMBER OF PAGES  4		
Drug Resistance, HIV,	16. PRICE CODE		
17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

## FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army.

Where copyrighted material is quoted, permission has been obtained to use such material.

where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

PI - Signature

Date

## **FINAL REPORT**

1. MIPR No. 92MM2549

2. Report Date:

15 May 1996

3. Reporting Period from:

1 April 1992

to:

3Ø April 1996

4. P.I.: Donald R. Skillman, LTC, MC 5. Phone (3Ø3) 361-8Ø14

DSN 943-8Ø14

6. Agency/ Address: Fitzsimons Army Medical Center

MCHG-MDI (Infectious Disease Service)

Aurora, CO 80045-5001

7. Project Title:

Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV

Infected Individuals Taking Antiretroviral Agents.

FAMC Protocol # 91/300

8. Current Staff, with percentage of effort on each project:

Donald R. Skillman, LTC, MC

Erin Palestro, R.N.

100%

9. MIPR Expenditures to date:

Personnel \$111,841. Supplies \$352,327.

Travel \$ 50,349. Other \$ 12,Ø23.

Equipment \$ 76,492. Contracts \$ 77,361.

Total

\$680,393.